510(k) Summary
510(k) Number K102123

Viztek, Inc.
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JAN 2 4 2011

Date Prepared: July 21, 2010
Contact: Bruce Ashby, Sales and Marketing Manager

1. **Identification of the Device:**
Proprietary-Trade Name: ViZion DR
Classification Name: Solid State X-Ray Imager (Flat Panel/Digital Imager) 90 MQB,
Common/Usual Name: Digital X-Ray Receptor Panel

2. **Equivalent legally marketed device:** Viztek DR, K082604 and Viztek Opal-RAD™ K063337. This new device employs the identical digital panel described in K090742, the Samsung Digital Flat Panel

3. **Indications for Use (intended use)** ViZion DR is intended for digital image capture use in general radiographic examinations for Adult and Pediatric wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

4. **Description of the Device:** The ViZion DR system represents the straightforward integration of two cleared devices. ViZion DR is a Digital Radiography system, featuring an integrated flat panel digital detector (FPD) K090742 (Samsung Flat-Panel X-Ray Detector), Samsung Mobile Display Co., Ltd. (this is the 510(k) for the flat panel detector) and Viztek's proprietary
OPAL-RAD PACS image viewing and acquire interface software technology, (K063337) which incorporates state of the art object-oriented software and connectivity.
ViZion is designed to perform digital radiographic examinations in replacement for conventional film. This integrated platform provides the benefits of PACS with the with the advantages of digital radiography for a filmless environment and improves cost effectiveness. The major functions and principle of operation of
the Viztek PACS and Samsung FPD were not changed.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and test laboratory indicates that the new device is as safe and effective as the predicate devices. Clinical images collected demonstrate equal or better image quality as compared to our predicates

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Viztek, LLC
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AUG 23 2013

Re: K102123
Trade/Device Name: ViZion DR, Digital Flat Panel X-Ray Detector System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: October 8, 2010
Received: October 14, 2010

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of January 24, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102123

Device Name: ViZion DR, Digital Flat Panel X-Ray Detector System

Indications For Use:

ViZion DR is intended for digital image capture use in general radiographic examinations for adult and pediatric, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis and extremities.

Prescription Use X AND/OR Over-The-Counter Use ___.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of In Vitro Diagnostic Devices (OVID)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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